K081976

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 28 2008

Submitted by:
**Agfa Healthcare Corporation**
**10 South Academy Street**
**Greenville, SC 29601**

1. **Date Prepared**
   January 28, 2008

2. **Contact Person**
   Patrick Lynch
   Phone: (864) 421-1987 FAX: (864) 421-1635

3. **Device Name and Classification**

| | |
|---|---|
| Trade Name: | IMPAX® MA3000 |
| Classification Name: | Picture archiving and communications system. |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR § 892.2050 |
| Device Class: | Class II |
| Device Code: | LLZ |

4. **Indications for Use**

   The **IMPAX MA3000** Diagnostic PACS Workstation is intended for use with regionally approved digital mammography modalities presenting processed images (DICOM "For Presentation" images) and the display of multi-modality general imaging DICOM images including adjunct breast imaging modality studies (i.e. Breast MR and Breast US).

   The **IMPAX MA3000** Diagnostic PACS Workstation when intended for diagnostic/screening Mammography viewing must do so only when used with FDA cleared monitors and only when viewing Lossless format images.

   The **IMPAX MA3000** Diagnostic PACS Workstation is also intended for soft and hardcopy reading and diagnosis by Radiologists.

5. **Substantial Equivalence**

   The predicate devices are:
   Agfa IMPAX Client Embrace™ (later renamed MA3000), K040555, May 26, 2004.
   McKesson Medical Imaging Company, Horizon Medical Imaging, K043146, January 4, 2005.

## 6. Device Description

IMPAX MA3000 is a diagnostic softcopy breast imaging workstation with diagnostic print capability.
The following features are available:
• Display and printing of regionally approved DICOM DR Digital Mammography Images
(MG SOP class)
• Display and printing of regionally approved DICOM CR Digital Mammography Images
(CR SOP class)

The Hardware configuration of Embrace™ will consist of the following:

| | |
|---|---|
| System (Per Host Machine): | Dell Precision™ Workstation 650; Compaq xw6000 |
| Number & Details of CPU's | 1 or 2 CPU's depending on configuration |
| Hard Drive space: | 40GB IDE |
| CD-ROM: | Yes |
| Floppy: | Yes |
| Network interfaces: | System comes with an integrated 10/100/1000 Ethernet adapter |
| Power Supplies: | Default |
| Chassis: | Tower |
| Peripherals: | Microsoft IntelliMouse or IntelliMouse Explorer; Keyboard |

Embrace™ will support the following monitors:

- BARCO Mammography MeDis 5MP CRT monitor package – MGD 521M
- BARCO Mammography 5MP and 3MP Flat Panel LCD's (EU)

**7. Comparison of Technological Differences:**

Technological and functional characteristics of Agfa's MA3000 software are identical to those of Horizon Medical Imaging and Client Embrace. Both of these workstations allow easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnostic imaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2008

Agfa HealthCare Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K081976
Trade/Device Name: IMPAX® MA3000
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 10, 2008
Received: July 11, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K081976

Device Name: **IMPAX® MA3000**

Indications For Use:

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| Prescription Use | AND/OR | Over-The-Counter Use |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | | (21 CFR 807 Subpart C) |
| ✓ | | |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081976